

Attorney Docket No.:	KUZ0032US.NP
Inventors:	Hashimoto et al.
Serial No.:	10/584,739
Filing Date:	June 26, 2006
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#### REMARKS

Claims 1-11 are pending in the instant application. Claims 1-11 have been rejected. Claim 1 has been amended. Claims 8 through 10 have been canceled without prejudice. Support for these amendments is provided in claims 8 through 10, now canceled. No new matter has been added. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### **I. Rejections of Claims 1-6, 8, 10 and 11 under 35 U.S.C 103(a)**

The rejection of claims 1-6, 8, 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over Tsuruda et al. (WO 01/68061 in view of Honda (U.S. Patent 5,637,293) has been maintained.

The rejection of claims 1-8, 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over Tsuruda et al. (WO 01/68061 in view of Yasukochi et al. (U.S. Patent Application Publication No. 2005/0053646) has also been maintained.

It is respectfully pointed out that claim 1 has been amended to include the recitation of the adhesive base

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containing a combination of a hydrogenated rosin ester and a terpene resin as set forth in claim 9, now canceled.

Claim 9 is not included in these rejections. Accordingly, this amendment is believed to render moot these rejections.

Withdrawal of these rejections is respectfully requested.

## II. Rejection of Claims 1-11 under 35 U.S.C. 103(a)

Claims 1-4 and 6-11 have been rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0109819 (hereinafter '819) in view of Tateishi.

Further, claim 5 has been rejected under 35 U.S.C. 103(a) as being unpatentable over '819 in view of Tateishi as applied to claim 1-4 and 6-11 and further in view of Honda.

Applicants respectfully traverse these rejections.

MPEP 2144.05 is clear; Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range. "The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a situation, the

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applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

In the instant application, claim 1 has been amended to recite a patch preparation comprising a support and an adhesive base, the adhesive base containing 8 to 50 mass % relative to total amount of the adhesive base of a rubber-system macromolecule having a double bond at least in a principal chain thereof and 0.1 to 10 mass % relative to entire amount of the preparation of a nonsteroidal anti-inflammatory analgesic drug **and a combination of a hydrogenated rosin ester and a terpene resin as a tackifier for 10 to 20 mass % in total relative to total amount of the adhesive base**, and the adhesive base further containing 0.5 to 20 mass % relative to entire amount of the preparation of a UVA blocker and/or a UVB blocker as a stabilizer for the rubber-system macromolecule. As taught in the specification at page 7, page 13 and page 14 and demonstrated in data set forth in Table 1 at page 19, the combination of a hydrogenated rosin ester and a terpene resin as tackifiers added in the amount of 10 to 20 mass % in total relative to total amount of the adhesive base prevents crystal of the

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UVA blocker and/or UVB blocker from precipitating in the adhesive base and prevents the adhesion from being degraded and maintains a high skin-penetrability for the non-steroidal anti-inflammatory analgesic drug without unnecessary increase in penetration of the UVA blocker and/or UVB blocker. Compare, for example Preparation 5 of Table 1 with only hydrogenated rosin ester at 11 % (no terpene resin) which exhibited less NSAID skin penetration to Preparation 9 of Table 1 with the claimed combination of terpene resin and hydrogenated rosin ester at 11% (within the claimed range). Also compare, for example Preparation 6 of Table 1 with only hydrogenated rosin ester at 8% which exhibited an unwanted increase in UVA blocker skin penetration as compared to Preparations 9, 10 and 11 of Table 1 with the claimed combination of hydrogenated rosin ester and terpene resin within the claimed 10 to 20% range.

The cited prior art does not teach or suggest the claimed range of the combination of a hydrogenated rosin ester and a terpene resin to achieve these unexpected results.

Instead, '819 teaches at paragraph [0024] that the tackifier is blended in an amount from 5 to 50% by mass, preferably, 7 to 45% by mass and, more preferably, 10 to 40%

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by mass. The '819 patent application teaches at paragraph [0024] that the tackifier is formulated such that viscosity and each tack are within a described range. Further, the '819 patent application teaches that with this blending ratio, tack, adhesion to skin, pains upon peeling and skin eruptions of skins can be improved greatly. The '819 patent application teaches that if the blending amount is less than 5% by mass, it is not preferred since the tack and the deposition to the skin is lowered. The '819 patent application teaches that if the blending amount is 50% by mass or more, it is not preferred since this lowers the shape retainability, and increase pain upon peeling, damages to keratin layers, skin eruptions and sliminess.

Nowhere does this patent application teach or suggest addition of the claimed combination of tackifiers in the amount of 10 to 20 mass % to prevent crystallization and/or precipitation of the UVA blocker and/or UVB blocker in the adhesive base or to maintain a high skin-penetrability for the non-steroidal anti-inflammatory analgesic drug. The instant claimed combination and range of 10 to 20 mass % tackifier clearly achieves unexpected results relative to the prior art range disclosed by '819.

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Tateishi teaches at paragraph [0042] that tackifier content based on the total composition of the pressure-sensitive adhesive layer is in the range of preferably 5-70 wt %, more preferably 5-60 wt % and even more preferably 10-50 wt %, taking into account adequate force as a patch and reducing irritation of the skin during peeling.

Accordingly, Tateishi also fails to teach or suggest addition of the claimed combination of tackifiers in the range of 10 to 20 mass % to prevent crystallization and/or precipitation of the UVA blocker and/or UVB blocker in the adhesive base or to maintain a high skin-penetrability for the non-steroidal anti-inflammatory analgesic drug. The instant claimed range of 10 to 20 mass % tackifier clearly achieves unexpected results relative to the prior art range disclosed by Tateishi.

Honda (U.S. Patent 5,637,293) provides no teaching or suggestion whatsoever with respect to tackifiers.

Thus, demonstration in the instant specification that the claimed range of a hydrogenated rosin ester and a terpene resin as a tackifier for 10 to 20 mass % in total relative to total amount of the adhesive base is critical to the unexpected results of preventing crystallization and/or precipitation of the UVA blocker and/or UVB blocker in the

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adhesive base and to maintaining a high skin-penetrability for the non-steroidal anti-inflammatory analgesic drug rebuts any prima facie obviousness over the cited combinations of 819 and Tateishi or '819, Tateishi and Honda. See MPEP 2144.05.

Further, MPEP 2145 states: "The totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986)". Applicants are providing herewith pages 93-94 of the Japan Adhesive Tape Manufacturer's Association and Handbook of Adhesion Editorial Committee, Handbook of Adhesion, Second Edition, Japan Adhesive Tape Manufacturers Association, October 12, 1995 (and an English language translation thereof) which sets forth the structures of terpene series resins. Clear from the formulas at page 93 is that terpene resins are non-polar resins as the hydrocarbon structure of the resin is not functionalized. Addition of a non-polar terpene resin to an adhesive base would be expected by the skilled artisan to decrease solubility of any polar ingredients. Accordingly, the skilled artisan would not be motivated to combine hydrogenated resin and terpene resin as in the instant claimed invention wherein prevention of

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crystallization of polar ingredients is a goal. Further, the demonstration in the instant specification, that inclusion of a hydrogenated rosin ester and a terpene resin as a tackifier for 10 to 20 mass % in total relative to total amount of the adhesive base is critical to preventing crystallization and/or precipitation of the UVA blocker and/or UVB blocker in the adhesive base and to maintaining a high skin-penetrability for the non-steroidal anti-inflammatory analgesic drug, is clearly unexpected over the well-established characteristic of terpene resins as non-polar resins. Applicants' inclusion of a non-polar terpene resin in the instant claimed patch preparation comprising an NSAID and a UVA blocker and/or a UVB blocker wherein crystal precipitation is undesirable was clearly a proceeding contrary to accepted wisdom in the prior art in its totality regarding terpene resins and thus serves as evidence of the nonobviousness of the instant claimed invention.

Withdrawal of these rejections under 35 U.S.C 103(a) is respectfully requested.

### III. Conclusion

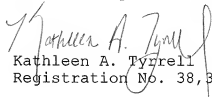
Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.



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Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
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## (b) テルペン樹脂

テルペン系樹脂の原料であるテレピン油には生松脂より得るガムテレピン油、クラフトパルプ製造時に副生するサルフェートテレピン油、および松根より溶剤抽出して得られるウッドテレピン油がある。これらテレピン油の組成は産地、松の種類によって差があるが主成分は $\alpha$ -ピネンと $\beta$ -ピネンである<sup>1)</sup>。その他柑橘類の果皮より得られるリモネンを主成分とするオレンジターペンがある。これらの構造は図12に示すとおりである。テルペン樹脂は主としてこれらの3種類のテルペンをフリーデル・クラフト触媒を用いて単独または共重合したものである。

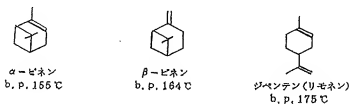


図12. テルペン系樹脂の原料となるテルペン

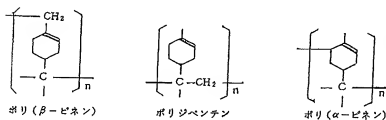


図13. 各テルペン樹脂の推定構造

テルペン樹脂の特徴は前述のように天然ゴムと構造的によく似ており、また天然ゴムとテルペン(テルペン樹脂)はともにイソプレンの重合体であるので相溶性がよい。このことは粘着剤の製造に際して広い濃度範囲で粘着特性のバランスが得易い。特に石油系の樹脂の欠点である低温時の粘着付与効果が顕著である。

それぞれ単独で重合された樹脂の推定構造は図13に示すとおりである。一般に $\beta$ -ピネン樹脂はジベンテン樹脂に比較して、同じ軟化点の場合平均分子量が大きく、タックを目的とする場合にはジベンテン樹脂が効果が大きく、粘着力、保持力を目的とする場合には $\beta$ -ピネン樹脂の方が効果が大きい。これら両者の共重合系における平均分子量と粘着特性は図14のとおりである。

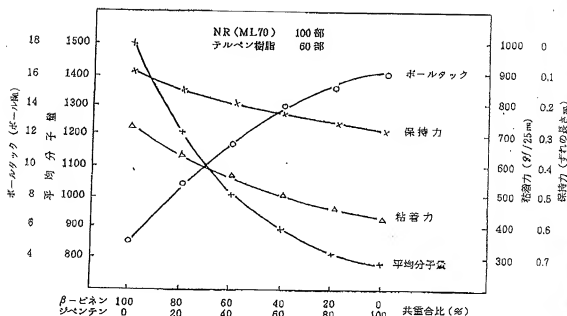


図14. β-ピネン・ジペンテン系樹脂の共重合比と粘着特性の関係

α-ピネン樹脂は一般的挙動はジペンテン樹脂に似ているが、ブチルゴム (IIR) より熱可塑性ブロックポリマーであるSBSまで相溶性がよく、SBR、SIS、SBSなどをエラストマとする粘着剤に対し粘着付与効果大きい。特にホットタイプSBRをエラストマとして使用した場合、80℃の耐熱老化テストにおいては他の樹脂の場合50時間でタック、粘着力ともに全くなくなるが、α-ピネン樹脂の場合200時間経過後もタックが若干減少する程度で粘着力には全く変化がない。

液状テルペン樹脂は軟化剤として使用する場合、保持力の低下が少なく、タックを与えるのに顕著な効果がある。唯一この液状テルペン樹脂の場合、加熱減量が若干大きいという問題がある。

#### (c) テルペンフェノール樹脂

テルペンフェノール樹脂はテルペンの種類、フェノールの種類およびフェノールの含有量により種々の樹脂が考えられるが、代表的な推定構造は図15に示すとおりである。一般にフェノール含有の少ない場合はゴム系エラストマの粘着付与剤の改質剤として、またフェノール含有の多いものは極性基を有するアクリル系またはEVA系の粘着付与剤として有効である。特にゴム系粘着剤の場合テルペン樹脂に併用すると、図16に示すようにタックを低下させることなく粘着力、保持力を向上させ得る。最適配合比はテルペン樹脂70%、テルペンフェノール樹脂30%程度である。その他普通天然ゴムと相溶性が悪いC<sub>3</sub>系石油樹脂に併用すること

(b) Terpene resin

Turpentines, raw materials of terpene series resin, comprises gum turpentines which could be obtained from raw pine resin, sulfate turpentines which is industrial coproduct of kraft pulp, and wood turpentines which could be obtained from the extraction of pine roots. In principle, the composition of these turpentines depend on growing area and species of the pine, principal components of them are  $\alpha$ -pinene and  $\beta$ -pinene. Another raw material of terpene series resin comprises orange terpene, of which a principal component is limonene obtained from peels of citrus. These structures are shown in fig. 12 below. Terpene resins are primarily produced by polymerization or co-polymerization of these three terpenes using Friedel-Crafts catalysts.

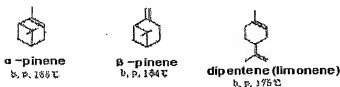


Fig. 12 Raw material terpenes of terpene series resins

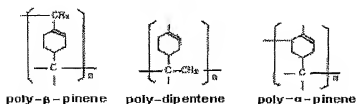


Fig. 13 Estimated structure of each terpene resins

The characteristics of terpene resins have good compatibility with natural rubber, since these structures are analogous each other and they are both polymers of isoprene. This characteristic allows them to obtain a balance of sticking properties in broad temperature range, in producing adhesives. In particular, there is a significant effect in tackifying at low temperature, which is a deficit of petroleum resins.

Estimated structures of each singulary polymerized terpene resins are shown in fig. 13. In general,  $\beta$ -pinene resins has a large average molecular weight compared to dipentene resins when softening point is the same, dipentene resins are useful for adding tackiness,  $\beta$ -pinene resins are useful for adding tack strength and retention strength. Average molecular weight and adhesive properties of these copolymerization system are shown in fig. 14.

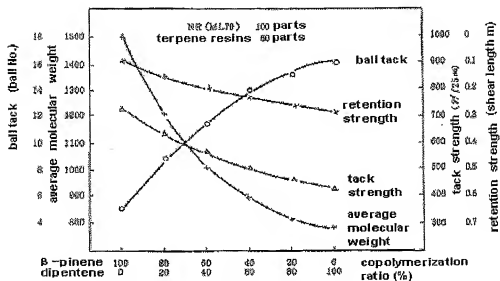


Fig. 14 The relationship of adhesive properties and copolymerization ratio of  $\beta$ -pinene /dipentene series resins

General behavior of  $\alpha$ -pinene resins are similar to dipentene resins, however, they have good compatibility with even from butyl rubber (IIR) to SBS which is a thermoplasticity block polymer, and also have a good tackifying effect to adhesives, of which elastomers are SBR, SIS, SBS and the like. In particular, when hot type SBR is used as an elastomer, an adhesive containing  $\alpha$ -pinene resin exhibits slight decrease in tackiness and no difference in tack strength even after 200 hours of heat-resistance retrograde test, while an adhesive containing the other resins exhibits tackiness and tack strength disappear after 50 hours of heat-resistance retrograde test.

Liquid terpene resins causes slight decreasing in retention strength and have significant effect in adding tackiness, when used as softening agent. Only with these liquid terpene resins, there is a problem that the loss on heating is somewhat large.